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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/729,133 | 12/05/2003 | Stephanie D. Waldrop | 22530-RA1 | 8985 |
| 30184 | 7590 | 06/03/2005 | EXAMINER | |
| MYERS & KAPLAN, INTELLECTUAL PROPERTY LAW, L.L.C. 1899 POWERS FERRY ROAD SUITE 310 ATLANTA, GA 30339 | | | ANTHONY, JOSEPH DAVID | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1714 | |

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,133

Applicant(s)

WALDROP ET AL.

Examiner

Joseph D. Anthony

Art Unit

1714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
4a) Of the above claim(s) 14 and 19-21 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-13 and 15-18 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL REJECTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because the claimed concentration ranges is improper because it relates to the concentration range of the ethylene oxide component when the claimed composition of independent claim 1 is being used in a sterilizing method and not to the concentration of the ethylene oxide component as found within the claimed composition of independent claim 1.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nimitz et al. U.S. Patent Number 5,674,451.

Nitmitz et al teaches sterilization compositions and methods of sterilization of articles using the same. The method comprises contacting an article with a blend comprising an ethylene oxide sterilant and a propellant which comprises a fluoroiodocarbon, such as trifluoroiodomethane. The propellant preferably comprises an admixture of a primary propellant and a fluoroiodocarbon, wherein the primary propellant can be carbon dioxide, nitrogen, hydrochlorofluorocarbons and/or hydrofluorocarbons. Carbon dioxide is a preferred primary propellant, see abstract, Table 4, and claims 1 and 4-9. Also see Example 13, which teaches a spray can of household disinfectant is pressurized with a mixture of 4% trifluoroiodomethane and 96% carbon dioxide. Because of the use of the fluoroiodocarbon blend as propellant, any flammability risk is eliminated. Likewise, EXAMPLE 14 teaches a gas mixture consisting of 5% (by moles) trifluoroiodomethane, 12% ethylene oxide, and 83% nitrogen is used to sterilize bandages, gauze pads, and medical equipment. Because of the addition of the

trifluoroiodomethane as a supplemental propellant, the danger of fire or explosion during the process is eliminated. Applicant's invention is deemed to be directly anticipated over Nimitz et al's Example 13 if the sterilant in Example 13 is actually ethylene oxide, the only sterilant species disclosed by the Nimitz et al's patent, but not directly stated in Example 13. In the alternative, applicant's invention is deemed to be extremely obvious over Nimitz et al's Example 13, since it would have been obvious to one having ordinary skill in the art to use ethylene oxide as the sterilant in the Example 13 since it is so well known in the art and is the only sterilant disclosed by the patent, see Example 14 and claim 1 for support. Furthermore, applicant's invention would be extremely obvious Example 14, when the nitrogen primary propellant is replaced by carbon dioxide as the primary propellant. Carbon dioxide is directly taught and claimed by Nimitz et al as a highly preferred primary propellant, see Example 13 and Claim 9 for support.

6. Claims 8-13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nimitz et al. U.S. Patent Number 5,674,451.

Nimitz et al has been described above and differ from applicant's claimed invention in that there is no direct teaching (i.e. by way of an example) to sterilizing compositions that actually further comprise one or more of the inert propellant/additives as set forth in these claims. It would have been extremely obvious to one having ordinary skill in the art to use one or more of applicant's

claimed inert propellant/additives, since such propellant/additives are directly disclosed and claimed by the Nimitz et al patent as useful additional components to the claimed sterilization method, see claims 1-10, especially claim 7, for direct support.

Response to Arguments

7. Applicant's arguments filed 03/17/05 have been fully considered but are not persuasive to put the application in condition for allowance for the reasons set forth above. Additional examiner comments are set forth next. The previously made provisional obvious type double patenting rejection over copending Application No. 10/752,291 has been dropped because the claims of said copending application have been amended to delete carbon dioxide from the "at least one physical combustion suppression agent". The previously made restriction is made final for the reasons of record.

Applicant's arguments that Example 13 of Nimitz et al is drawn to a disinfectant and not to a sterilant, which is supported by applicant's cited article having dictionary definitions of these terms, is noted but is deemed to be totally irrelevant in regards to the appropriateness of the examiner made anticipated rejection. In the first place, one would know that to disinfect an article would inherently sterilize the article, since to disinfect means to kill the harmful microorganism which would inherently prevent it from producing offspring which is the definition of to sterilize. Furthermore, the abstract of the Nimitz et al patent

uses the word "sterilization" to describe the compositions set forth in Examples 13-14.

Applicants argue that their composition is patentable because it has been amended to be synergistic. Applicant directly stated in Applicant's Supplemental Declaration filed under 37 CFR 1.67 that: "Had such synergistic results been obvious there would have been no need to spend the extensive time and effort in finding that the compositions disclosed in U.S. Patent Appl. No. 10/729133 were synergistic.". Applicant's Supplemental declaration filed under 37 CFR 1.67 is deemed not to overcome the alternative obvious type rejection over the Nimitz et al patent because the compositions taught and disclosed by the applied Nimitz et al patent can also be synergistic in nature as are the compositions in applicant's amended claims. Applicant's attention is drawn to Nimitz et al's column 14, lines 54-58 wherein it is taught: "In some cases these blended agents provide synergism (better extinguishment than predicted linearly) because of the chemical extinguishment of the fluoroiodocarbon and the physical extinguishment of the additive." Also see Table 4 in column 13 of the patent which lists carbon dioxide, a well-known physical combustion suppressant, a preferred component to be blended with trifluoroiodmethane. As such it is deemed that applicant did not discover synergism subsequent to the patenting of the applied Nimitz et al patent. In any case, the courts have constantly declared that to discover a new property in an otherwise old composition does not make the composition itself patentable.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner Information

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Joseph D. Anthony whose telephone number is (571) 272-1117. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on (571) 272-1119. The centralized FAX machine number is (703) 872-9306. All other papers received by FAX will be treated as Official communications and cannot be immediately handled by the Examiner.

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A handwritten signature in black ink, appearing to read "Joseph D. Anthony", with a stylized, sweeping flourish at the end.

Joseph D. Anthony
Primary Patent Examiner
Art Unit 1714

5/31/05